

REMARKS

Claims 1-24, 27-30 and 36-47 are pending.

Claims 1-7, 29-30, 42-45, and 47 have been rejected as allegedly anticipated under 35 U.S.C. § 102(b) over U.S. Patent No. 5,037,845 to Oxford et al. (“*Oxford*”). Claims 1-24, 27-30 and 36-47 have been rejected as allegedly obvious under 35 U.S.C. § 103(a) over *Oxford* in view of secondary references (*Brittain, Dorsey, and Vogel*). Claims 1-7, 13-20, 29-30, and 40-42 have been rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement. Claims 8, 12, 24, and 27 have been rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite.

Applicants make reference to the decision of the Board of Patent Appeal and Interferences in *Ex Parte Buchi* (September 6, 2007), a copy of which is attached for immediate reference. Applicants respectfully assert that *Ex Parte Buchi* has direct bearing on the resolution of issues in the present patent application.

Applicants respectfully request reconsideration and allowance of all pending claims in view of the remarks set forth below.

I. ANTICIPATION REJECTION OVER OXFORD

The Examiner has rejected claims 1-7, 29-30, 42-45, and 47 as allegedly anticipated by *Oxford*. According to the Examiner, *Oxford*’s Example 19 describes a solid identical to the succinate salt of sumatriptan claimed in the present patent application. The Examiner appears to suggest that Example 19 of *Oxford* inherently anticipates the claimed salt of sumatriptan.

Applicants strongly and respectfully disagree.

*Oxford*’s Example 19 discloses crystallization of sumatriptan succinate from IMS (industrial methylated solids). See *Oxford*, col. 26, line 12. In contrast, none of the solvents disclosed in the present application for preparation of the claimed solids is IMS. Moreover, while not critical to patentability, none of the solvents disclosed in the present patent application belong to the same solvent class as IMS.

First, to establish a *prima facie* case of inherent anticipation, the Examiner must show scientific rationale or objective evidence tending to show inherency. See MPEP §2112. See also

*Ex parte Buchi*, Sl. Op., at p. 6. Only then the burden will shift to the Applicants to disprove the inherency. See *Ex Parte Buchi*, Sl. Op., at page 7, citing, *Ex Parte Skinner*, 2 USPQ.2<sup>nd</sup> (BNA) 1788 (BPAI 1986).

In the present case, as in *Buchi*, the evidence adduced by the Examiner does not justify shifting of the burden. Quite clearly, the preparation methodologies disclosed in the present patent application are different from the Example 19 of *Oxford*. Compare *Ex Parte Bucchi*, Sl. Op. at page 7. Moreover, none of the solvents belong to the same solvent class. Compare *id.*

Second, to establish inherency, the reference's teachings or extrinsic evidence "must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and it would be so recognized by persons of ordinary skill." See *In re Robertson*, 49 U.S.P.Q.2d (BNA) 1949, 1950-51 (Fed. Cir. 1999), cited in MPEP §2112. What would be the objective evidence of inherency in view of *Oxford*'s teaching of a different isolation methodology? Why would one skilled in the art recognize that *Oxford*'s procedure would necessarily result in the claimed solids?

Withdrawal of the anticipation rejection over *Oxford* is respectfully requested.

## II. OBVIOUSNESS REJECTION OVER OXFORD IN VIEW OF SECONDARY REFERENCES

The Examiner has made an obviousness rejection over *Oxford* in view of secondary references. For example, the Examiner suggests that since *Brittain* teaches the desirability of screening for polymorphs, all new polymorphs are *prima facie* obvious. In essence, the Examiner suggests that any new polymorph of a known compound is *prima facie* obvious, absent showing of unexpected results. See, e.g., Office Action, at page 7.

Applicants strongly and respectfully disagree.

To establish a *prima facie* case of obviousness, the Examiner must show that one skilled in the art would have reasonable expectation of success to modify *Oxford*. Typically, an artisan does not have such requisite expectation of success when setting out to make new polymorphs of an existing compound. Applicants submit herewith:

- a) An article by A. Goho;

- b) An article by J. Dunitz and J. Bernstein, and
- c) An article by R. J. Davey.

Together, these articles clearly illustrate the present state of the art and demonstrate that, currently, the prediction of an existence of a polymorph, let alone the prediction of the specific polymorphic state, is not possible. *See MPEP §2142.02, citing, In re Rinehart*, 189 USPQ (BNA) 143 (CCPA 1976) (“Evidence showing there was no reasonable expectation of success may support a conclusion of non-obviousness.”). Clearly, existence of one crystalline form of solid provides no reasonable expectation of success whatsoever to make any new polymorph, let alone to make the specific polymorph claimed. Applicants note it is the latter that is required: there must be a reasonable expectation of success to make the invention, i.e., the specifically claimed polymorph. Compare this requirement with the state of art’s (see attached articles) evidence about discovery of new polymorphs after considerable period of time and disappearance of a previously identified polymorph.

Therefore, it is not surprising that the Board of Patent Appeals and Interferences has rejected a conclusion of obviousness in circumstances greatly similar to the circumstances in the present patent application. *See Ex Parte Buchi*, Sl. Op., at pages 8-9. In *Buchi*, the Examiner cited Cheronis as a secondary reference to show that use of re-crystallization is well known in the art and finding obviousness of the basis of combining Cheronis with a primary reference that taught a crystalline solid. In other words, the Examiner in *Buchi* argued that since re-crystallization is known, an artisan would employ it to arrive at the claimed polymorph. The Board rejected this reasoning, stating that while one would be expected to purify by crystallization, “that would not necessarily lead to the claimed crystalline forms.” *Id.*, at p. 9.

It is precisely one of the issues in the present patent application. While an artisan may be expected to search for polymorphs (as arguably suggested by *Brittain*), an artisan will not have a reasonable expectation of success in finding any polymorph, and will certainly not have such expectation with respect to the specific polymorph claimed.

Withdrawal of all rejections over *Oxford* is respectfully requested.

### III. ENABLEMENT REJECTIONS

The Examiner has rejected Claims 1-7, 13-20, 29-30, and 40-42 for alleged lack of enablement.

Applicants respectfully disagree.

The bases for this rejection are not clear to the Applicants.

The test for enablement is well established. The issue is whether the disclosure, as filed, enables an artisan to make and use the claimed invention. *See MPEP §2164.01*. In the present patent application, it is not clear how this test may be not satisfied.

For example, the rejected claim 1 recites a crystalline form I of sumatriptan succinate. The method of making it is provided in the specification of the present patent application. *See, e.g., Examples 2 and 3*. Also, it is known how to use sumatriptan succinate. Thus, the issue of undue experimentation should not even arise. *Cf. e.g., Ex Parte Buchi, Sl. Op. at pages 3-4*.

Withdrawal of the enablement rejection is respectfully requested.

### IV. INDEFINITENESS REJECTION

Claims 8, 12, 24, and 27 have been rejected as allegedly indefinite. According to the Examiner, the term “highly pure” is not defined in the specification. In particular, the Examiner objects to the specification’s statement that “the term ‘highly pure’ means at least about 99% pure by HPLC, more preferably, at least about 99.5% pure . . .” Applicants respectfully maintain that the meaning “of least about 99% pure by HPLC” would be clear to one skilled in the art. With respect to the language that begins with “most preferably,” Applicants respectfully maintain that that language would be understood, in the context of the specification as a whole, to refer to the purity of the solid rather than the definition of the claim term.

Withdrawal of the indefiniteness rejection is respectfully requested.

In view of the foregoing, the Applicants submit that all claims are in condition for allowance. Accordingly, both reconsideration of this application and its swift passage to issuance are earnestly solicited. In the event that there are any fees due and owing in connection with this matter, please charge the same to our Deposit Account No. 50-3221.

Respectfully submitted,

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